# Decision Memo for Serum Iron Studies NCD 190.18 (Addition of ICD-9-CM diagnosis code 285.22 Anemia of Malignancy and 285.29 Anemia of Other Chronic Condition) (CAG-00406N)

## Decision Summary

CMS has determined that ICD-9-CM diagnosis codes, 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions, flow from the existing narrative for conditions for which a Serum Iron Study is reasonable and necessary. Consequently, ICD-9-CM diagnosis codes 285.22 and 285.29 shall be added to the list of "ICD-9-CM Codes Covered by the Medicare Program" for the national coverage determination (NCD) for Serum Iron Studies, as stated in Section 190.18 of the NCD Manual.

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## Decision Memo

**This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of CPT/HCPCS codes that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-04, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.**

TO: Administrative File: CAG-00406L
Serum Iron Studies NCD 190.18 (Addition of ICD-9-CM diagnosis codes 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions)

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SUBJECT: Serum Iron Studies NCD 190.18 (Addition of ICD-9-CM diagnosis codes 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions)

DATE: December 18, 2008

## I. Decision

CMS has determined that ICD-9-CM diagnosis codes, 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions, flow from the existing narrative for conditions for which a Serum Iron Study is reasonable and necessary. Consequently, ICD-9-CM diagnosis codes 285.22 and 285.29 shall be added to the list of “ICD-9-CM Codes Covered by the Medicare Program” for the national coverage determination (NCD) for Serum Iron Studies, as stated in Section 190.18 of the NCD Manual.

## II. Background

Section 190.18 of the NCD Manual states that serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron studies are best performed when the patient is fasting in the morning and has abstained from medications that may influence iron balance.

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption.

Following major surgery the patient may have iron deficient erythropoiesis for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

Total iron binding capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, with oral contraceptive use and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

Assays for ferritin are also useful in assessing iron balance. Low concentrations are associated with iron deficiency and are highly specific. High concentrations are found in hemosiderosis (iron overload without associated tissue injury) and hemochromatosis (iron overload with associated tissue injury). In these conditions the iron is elevated, the TIBC and transferrin are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload.

Transferrin and ferritin belong to a group of serum proteins known as acute phase reactants and are increased in response to stressful or inflammatory conditions and also can occur with infection and tissue injury due to surgery, trauma or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions and in patients with these disorders, tests of iron status may be difficult to interpret.

## III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare Program” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes that Do Not Support Medical Necessity” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

Also, the negotiating committee developed a list of “descriptors” for each of the 23 laboratory NCDs, which listed the CPT or other Health Care Procedure Coding System (HCPCS) codes for which the particular NCD applied. These codes described the procedures or services that a physician or other provider may deliver to a patient under the auspices of our NCD and flow from the narrative descriptions of the test indicated in the NCD. The CPT is developed and copyrighted by the American Medical Association.

## IV. Timeline of Recent Activities

On November 5, 2008, CMS formally accepted a request for consideration to add ICD-9-CM diagnosis codes 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions, to the list of diagnosis codes covered by Medicare for the Serum Iron Studies NCD.

We posted a tracking sheet to the Internet at (https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=226) and solicited public comments for 30 days on the appropriateness of the addition of codes 285.22 and 285.29 to the Serum Iron Studies NCD. CMS received two comments from two organizations during the public comment period and both support adding the codes.

CMS received one public comment from America’s Health Insurance Plans (AHIP). AHIP encourages CMS to ensure that all patients receive the most effective and appropriate treatments as supported by sufficient levels of clinical evidence and therefore supports the inclusion of both codes since they are consistent with the *Indications and Limitations of Coverage* within the NCD. The second public comment came from the American Society of Hematology (ASH). ASH indicated its support of CMS’ addition of both codes. ASH stated that serum iron studies are important in the evaluation of anemia and that it is important for patients with anemia due to malignancy and other chronic conditions to have access to this diagnostic tool.

## V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process. We call this abbreviated process the Coding Analysis for Laboratories (CAL) process.

## VI. CMS Analysis

The NCD includes the narrative indications and limitations below. We consider here whether serum iron studies for anemia of malignancy and anemia of other chronic conditions flow from this narrative.

Indications

1.

Ferritin, iron and either iron binding capacity or transferrin are useful in the differential diagnosis of iron deficiency, anemia, and for iron overload conditions.

a. The following presentations are examples that may support the use of these studies for evaluating iron deficiency: certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV); abnormal appetite (pica); acute or chronic gastrointestinal blood loss; hematuria; menorrhagia; malabsorption; status post-gastrectomy; status post-gastrojejunostomy; malnutrition; preoperative autologous blood collection(s); malignant, chronic inflammatory and infectious conditions associated with anemia which may present in a similar manner to iron deficiency anemia; following a significant surgical procedure where blood loss had occurred and had not been repaired with adequate iron replacement.

b.

The following presentations are examples that may support the use of these studies for evaluating iron overload:chronic hepatitis; diabetes; hyperpigmentation of skin; arthropathy; cirrhosis; hypogonadism; hypopituitarism; impaired porphyrin metabolism; heart failure; multiple transfusions; sideroblastic anemia; thalassemia major; cardiomyopathy, cardiac dysrhythmias and conduction disturbances.

2.

Follow-up testing may be appropriate to monitor response to therapy, e.g., oral or parenteral iron, ascorbic acid, and erythropoietin.

3.

Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.

4.

Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.

5.

Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, lead) whether due to accidental, intentional exposure or metabolic causes.

Limitations

1.

Iron studies should be used to diagnose and manage iron deficiency or iron overload states. These tests are not to be used solely to assess acute phase reactants where disease management will be unchanged. For example, infections and malignancies are associated with elevations in acute phase reactants such as ferritin, and decreases in serum iron concentration, but iron studies would only be medically necessary if results of iron studies might alter the management of the primary diagnosis or might warrant direct treatment of an iron disorder or condition.

2.

If a normal serum ferritin level is documented, repeat testing would not ordinarily be medically necessary unless there is a change in the patient's condition, and ferritin assessment is needed for the ongoing management of the patient. For example, a patient presents with new onset insulin-dependent diabetes mellitus and has a serum ferritin level performed for the suspicion of hemochromatosis. If the ferritin level is normal, the repeat ferritin for diabetes mellitus would not be medically necessary.

3.

When an End Stage Renal Disease (ESRD) patient is tested for ferritin, testing more frequently than every three monthsrequires documentation of medical necessity (e.g., other than chronic renal failure or renal failure, unspecified).

4.

It is ordinarily not necessary to measure both transferrin and TIBC at the same time because TIBC is an indirect measure of transferrin. When transferrin is ordered as part of the nutritional assessment for evaluating malnutrition, it is not necessary to order other iron studies unless iron deficiency or iron overload is suspected as well.

5.

It is not ordinarily necessary to measure both iron/TIBC (or transferrin) and ferritin in initial patient testing. If clinically indicated after evaluation of the initial iron studies, it may be appropriate to perform additional iron studies either on the initial specimen or on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferrin) or ferritin may be medically necessary for monitoring, but not both.

6.

It would not ordinarily be considered medically necessary to do a ferritin as a preoperative test except in the presence of anemia or recent autologous blood collections prior to the surgery.

We note that “anemia” is a covered indication in the narrative, and the narrative includes malignancy, chronic inflammation and chronic infection as examples of conditions that may present in a manner consistent with iron deficiency anemia. Therefore, CMS has determined that ICD-9-CM diagnosis codes, 285.22, Anemia of Malignancy and 285.29, Anemia of Other Chronic Conditions, flow from the existing narrative for conditions for which a Serum Iron Studies test is reasonable and necessary. Consequently, ICD-9-CM diagnosis codes 285.22 and 285.29 shall be added to the list of “ICD-9-CM Codes Covered by the Medicare Program” for the national coverage determination (NCD) for Serum Iron Studies, as stated in Section 190.18 of the NCD Manual.

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